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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,819	06/26/2003	Thomas Nilsson	239639US8	2765

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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/603,819	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 43-57 are pending. Applicants have cancelled claims 21-42. Claims 43-57 are new. Receipt and consideration of Applicants' arguments/remarks, new IDS (submitted on 8/31/07), and amendments filed on August 7, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 7, 2007 has been entered.

Moot Rejections/objections

All rejections and/or objections of claims 21-42 cited in the previous office action mailed on January 3, 2007 **are moot**, because said claims have been cancelled.

Specification

The objection to the disclosure because of the following informality: the title of the disclosure on page 1 is missing the letter "o" in the word "administration" **is withdrawn**, per Applicants' amendment correcting said informality.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting cited on pages 14-19 of the office action mailed on 1/12/06 and maintained on page 11 of the office action mailed on 6/28/06 (i.e. rejections over copending applications: 10/703,505; 10/728,986; 10/870,907; 10/870,909; 10/870,945; 10/921,192; 11/085,523; 11/049,696; 11/111,888; and 11/272,859) **are withdrawn** per Applicants' claim amendments or because the cited copending application has been abandoned. It is noted that copending applications (1) 10/703,505; (2) 10/870,907; (3) 10/870,909; and (4) 10/870,945 have been abandoned.

Response to Arguments

Applicant's arguments, see page 9 of the remarks, filed July 2, 2007, with respect to the above-cited provisional rejections on the ground of nonstatutory obviousness-type

double patenting have been fully considered and are persuasive. The above-cited provisional rejections on the ground of nonstatutory obviousness-type double patenting have been withdrawn.

Claims 43-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-9 of U.S. Patent No. 6,840,239 (USPN '239) in view of Davies et al. (US 2002/0053344). Independent claim 43 of the instant application claims a method of administering a metered dry powder combined dose comprising providing a relative motion between a nozzle of a dry powder inhaler and a dose bed carrying said combined dose, wherein the combined dose comprises metered quantities of at least two medicaments separately deposited on the dose bed and the relative motion causes the nozzle to pass over the combined doses for a simultaneous or sequential deliver of the medicaments during the course of a single suction of air. Independent claim 1 of USPN '239 claims a method of de-aggregating and dispersing into air a dose of finely divided medication powder, releasably maintained onto a substrate member comprising (i) providing a nozzle comprising an inlet and an outlet and positioning said nozzle inlet aperture adjacent to or in contact with the substrate member; (ii) applying suction of air to the nozzle outlet; (iii) introducing a relative motion between the nozzle and the substrate member, such that the nozzle inlet aperture traverses the dose of inlet divided medication powder, and (iv) de-aggregating particle aggregates within the dose of finely divided medication powder. Dependent claim 8 of USPN '239 further limits claim 1 of USPN '239 to further include the step of depositing at least one finely divided medication powder onto a first or a second side or

both sides of the substrate member. Dependent claim 9 of USPN '239 indicates that the deposited finely divided medication powder optionally comprises different medicament powders. The cited claims of USPN '239 do not recite specific powdered medicament combinations, however this deficiency is cured by the teachings of Davies. Davies teaches a variety of powdered medicaments suitable for inhalation (e.g. formoterol fumarate, budesonide, fluticasone propionate, ipratropium bromide, tiotropium, albuterol [also known as salbutamol]) which may be used in combination (see paragraphs 92-94). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 43-57 *prima facie* obvious over claims 1 and 8-9 of U.S. Patent No. 6,840,239 (USPN '239) in view of Davies et al. (US 2002/0053344).

Claims 43-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,881,398 (USPN '398) in view of Davies et al. (US 2002/0053344) and Radhakrishnan et al. (U.S. Patent No. 5,192,528) (IDS). Independent claim 43 of the instant application claims a method of administering a metered dry powder combined dose comprising providing a relative motion between a nozzle of a dry powder inhaler and a dose bed carrying said combined dose, wherein the combined dose comprises metered quantities of at least two medicaments separately deposited on the dose bed and the relative motion causes the nozzle to pass over the combined doses for a simultaneous or sequential deliver of the medicaments during the course of a single suction of air. Independent claim 1 of USPN '398 claims a method of de-aggregating and dispersing into air a dose of finely divided medication powder, releasably maintained onto a substrate member

comprising (i) providing a metered dose of the therapeutic dry powder on a surface substrate, (ii) providing an inhaler constructed to receive the substrate, the inhaler being constructed and arranged so as to allow relative movement between a nozzle and the substrate; and (iii) having the user inhaler through a mouthpiece connected to the nozzle while the nozzle moves with respect to the substrate so as to release, de-aggregate, disperse into air, and deliver the therapeutic dry powder, wherein the therapeutic powder comprises at least one finely divided, pharmacologically active substance, and wherein the active substance as it is delivered to the used comprises at least 50% fine particle fraction, with fine particle fraction (FPF) defined as a fraction of the active substance by mass with a maximum aerodynamic particle size of 5 microns. The cited claim of USPN '398 does not recite any specific powdered medicament combinations, FPF, or particle size of the powdered medicament, however this deficiency is cured by the teachings of Davies and Radhakrishnan. Davies teaches a variety of powdered medicaments suitable for inhalation (e.g. formoterol fumarate, budesonide, fluticasone propionate, ipratropium bromide, tiotropium, albuterol [also known as salbutamol]) which may be used in combination (see paragraphs 92-94). Radhakrishnan teaches in Fig. 1 the MMAD particle sizes and the different stages of the Anderson Cascade Impactor, corresponding to regions of the pulmonary system where particles of different sizes are delivered. For example, mist particle sizes of greater than about **2-3 microns** are deposited predominantly in the **upper regions of the respiratory tract**, whereas particle sizes less than about 2 microns favor deposition in the **lower pulmonary regions**, including deep lung or parenchymal lung sites (col. 1, lines 69 and col. 2, lines 1-5). The three lower regions of the respiratory tract encompassing the bronchi and alveoli are reached by

particles with sizes between about **0.43 and 0.65 microns** (stage 7 alveoli), **0.65 and 1.1 micron** (stage 6 alveoli), and **1.1 and 2.1 microns** (terminal bronchi). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 43-57 *prima facie* obvious over claim 1 of U.S. Patent No. 6,881,398 (USPN '398) in view of Davies et al. (US 2002/0053344) and Radhakrishnan et al. (U.S. Patent No. 5,192,528).

Claims 43-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 20-21 of U.S. Patent No. 6,892,727 (USPN '727) in view of Davies et al. (US 2002/0053344). Independent claim 43 of the instant application claims a method of administering a metered dry powder combined dose comprising providing a relative motion between a nozzle of a dry powder inhaler and a dose bed carrying said combined dose, wherein the combined dose comprises metered quantities of at least two medicaments separately deposited on the dose bed and the relative motion causes the nozzle to pass over the combined doses for a simultaneous or sequential deliver of the medicaments during the course of a single suction of air. Independent claim 13 of USPN '727 claims a device for de-aggregating and dispersing into air a dose of finely divided medication powder, releasably maintained onto a substrate member wherein when a suction of air is applied to a nozzle the nozzle moves with respect to the substrate so as to release, de-aggregate, disperse into air, and deliver the therapeutic dry powder. The cited claims USPN '727 do not recite any specific powdered medicament combinations and this deficiency is cured by the teachings of Davies. Davies teaches a variety of powdered medicaments suitable for

inhalation (e.g. formoterol fumarate, budesonide, fluticasone propionate, ipratropium bromide, tiotropium, albuterol [also known as salbutamol]) which may be used in combination (see paragraphs 92-94). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 43-57 *prima facie* obvious over claims 13 and 20-21 of U.S. Patent No. 6,892,727 (USPN '727) in view of Davies et al. (US 2002/0053344).

Conclusion

Claims 43-57 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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